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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Norihito Ohi

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06/26/2006

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EXAMINER

NOLAN, JASON MICHAEL

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/509,795	Applicant(s) OHI ET AL.	
	Examiner Jason M. Nolan, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-61 are currently pending in the instant application and are subject to a lack of unity restriction requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Claims 1-61 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

- (i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or
- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or

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(iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to numerous and widely divergent variables in the substituents, for example: **Cy, V, and R¹**, and the numerous and widely divergent methods of use present, a precise listing of inventive groups cannot be made. The following groups are exemplary:

Group I, Claims 1-4, 24-48, and 50, drawn to products of the Formula I, wherein **Ar** is a C₆₋₁₄ aryl group and **Cy** is a 5-membered heteroaryl group.

Group II, Claims 1-4, 24-48, and 50, drawn to products of the Formula I, wherein **Ar** is a C₆₋₁₄ aryl group and **Cy** is a 6-membered heteroaryl group.

Group III, Claims 1-4, 24-48, and 50, drawn to products of the Formula I, wherein **Ar** is a 5-14-membered heteroaryl group and **Cy** is a 5-membered heteroaryl group.

Group IV, Claims 1-4, 24-48, and 50, drawn to products of the Formula I, wherein **Ar** is a 5-14-membered heteroaryl group and **Cy** is a 6-membered heteroaryl group.

Group V, Claims 5-19, drawn to products of the Formula II, wherein **Ar** is a C₆₋₁₄ aryl group.

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Group VI, Claims 5-19, drawn to products of the Formula II, wherein **Ar** is a 5-14-membered heteroaryl group.

Group VII, Claims 5-19, drawn to products of the Formula III, wherein **Ar** is a C₆₋₁₄ aryl group.

Group VIII, Claims 5-19, drawn to products of the Formula III, wherein **Ar** is a 5-14-membered heteroaryl group.

Group IX, Claims 51-61, drawn to compositions and methods of use for the compounds of formula I.

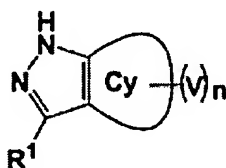
In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, this is not an exhaustive list, as it would be impossible to produce such a list under the time constraints due to the large volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention (a product, a process of making the product and a method of use) by identifying another specific embodiment, i.e. a group containing the variables **Cy, V, and R¹**, not listed in the exemplary groups of the invention and Examiner will endeavor to group the same. The applicant may also choose to elect a single disclosed species or a single method of use of a single species and the Examiner will endeavor to create a group comprising the elected species.

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. 1.475(a) **Group I - Group IX** lack unity of invention since, under 37 CFR 1.475:

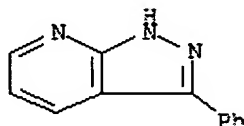
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Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The structural moiety common to **Groups I-IX** is the structural core shown below.



This technical feature is not a special technical feature, because it fails to define a contribution over the prior art shown below, (see Ortoleva, G. *Gazzetta Chimica Italiana* (1908), 37(2), 71-82).



Therefore, **Claims 1-61** are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a whole result in vastly different compounds. Specifically, the products of Formulae I-III introduce moieties **Cy** and **R¹**, wherein the structure may contain a nitrogen atom, a carbon atom, or an oxygen atom, resulting in patentably distinct structural cores. Furthermore, changes such as these affect the structural element shared by the products of Formulae I-III, and represent a different class of chemical compounds in the pharmaceutical art. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject

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matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a product and a method of use.

Furthermore, with respect to **Group I – Group IX**, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specially designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c),

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than a product and a method of use, and according to 37 CFR 1.475(e),

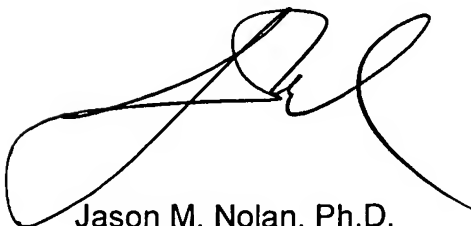
The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

As a result, the claims lack unity of invention and applicant is required to elect a single invention.

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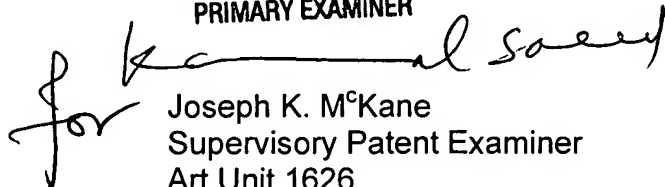
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is **Jason.Nolan@uspto.gov**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph M^cKane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Examiner
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Date: June 21, 2006